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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/705,401	11/10/2003	Henrik Clausen	04305/100H154-US2	4414
7278 7590 04/20/2007 DARBY & DARBY P.C. P. O. BOX 5257 NEW YORK, NY 10150-5257			EXAMINER FRONDA, CHRISTIAN L	
			ART UNIT	PAPER NUMBER
			1652	
SHORTENED STATUTORY PERIOD OF RESPONSE		MAIL DATE	DELIVERY MODE	
3 MONTHS		04/20/2007	PAPER	

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

# Office Action Summary

Application No.

10/705,401

Applicant(s)

CLAUSEN ET AL.

Examiner

Christian L. Fronda

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 22 January 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-43 is/are pending in the application.
- 4a) Of the above claim(s) 1-4 and 9-40 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 5, 7 and 8 is/are rejected.
- 7) ☒ Claim(s) 6 and 41-43 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 10 November 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

## Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

## Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_

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### **DETAILED ACTION**

1. Claims 1-43 are pending in the instant application. Claims 1-4 and 9-40 have been previously withdrawn as being directed toward a non-elected invention.
2. Claims 5-8 and 41-43 are under consideration in this Office Action
3. The objection to claims 5-8 because the claims recite the abbreviation "GalNAc-transferase" without defining it has been withdrawn in view of applicants' amendment to the claims filed 01/22/2007.
4. The rejection of claim 6 has been withdrawn in view of applicants' amendment to the claim filed 01/22/2007.

#### ***Claim Rejections - 35 U.S.C. § 112, 2nd Paragraph***

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:  
The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.
6. Claims 7 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.  
In claim 7 the phrase "comprising 10-20 amino acid residues of the corresponding UDP-GalNAc:polypeptide N-acetylgalactosaminyltransferase" renders the claim vague and indefinite since it is not certain what specific enzyme and its specific amino acid sequence and structure is being referred to.

#### ***Claim Rejections - 35 U.S.C. § 112, 1st Paragraph***

7. The following is a quotation of the first paragraph of 35 U.S.C. 112:  
The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of

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carrying out his invention.

8. Claims 5, 7, and 8 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Applicants' arguments filed 01/22/2007 that the claims are adequately described by the specification have been considered but are not persuasive for the reasons of record as supplemented below.

The amended claims are drawn to a genus of isolated lectin polypeptides of any amino acid sequence and structure consisting of any truncated mammalian UDP-GalNAc:polypeptide N-acetylgalactosaminyltransferase comprising any domain selected from the group consisting of the lectin domain of any mammalian UDP-GalNAc:polypeptide N-acetylgalactosaminyltransferase, any lectin-functional variant and fragments thereof. The scope of each genus includes many members with widely differing structural, chemical, and physiochemical properties including widely differing nucleotide sequences and biological functions. Furthermore, each genus is highly variable because a significant number of structural and biological differences between genus members exist.

For claims drawn to a genus, MPEP § 2163 states the written description requirement for a claimed genus may be satisfied through sufficient description of a representative number of species by actual reduction to practice, reduction to drawings, or by disclosure of relevant, identifying characteristics, i.e., structure or other physical and/or chemical properties, by functional characteristics coupled with a known or disclosed correlation between function and structure, or by a combination of such identifying characteristics, sufficient to show that applicant was in possession of the claimed genus. See *Eli Lilly*, 119 F.3d at 1568, 43 USPQ2d at 1406. MPEP § 2163 states that a representative number of species means that the species which are adequately described are representative of the entire genus. Thus, when there is substantial variation within the genus, one must describe a sufficient variety of species to reflect the variation within the genus.

The specification discloses in Example 3 HIS-tagged truncated GalNAc-T2 and -T4 lectins consisting of the SEQ ID NO: 99 and SEQ ID NO: 103, respectively. However, the specification fails to disclose additional species as encompassed by the claimed genus, which are widely variant in their physiological characteristics, functions, and/or structures. As such the disclosure of the above mentioned species is insufficient to be representative of the attributes and features common to all the members of the claimed genus. Thus, one skilled in the art cannot visualize or recognize the identity of the members of the genus.

In view of the above considerations, one of skill in the art would not recognize that applicants were in possession of a genus of isolated lectin polypeptides of any amino acid

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sequence and structure consisting of any truncated mammalian UDP-GalNAc:polypeptide N-acetylgalactosaminyltransferase comprising any domain selected from the group consisting of the lectin domain of any mammalian UDP-GalNAc:polypeptide N-acetylgalactosaminyltransferase, any lectin-functional variant and fragments thereof.

9. Claims 5, 7, and 8 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for an isolated lectin polypeptide having an amino acid sequence selected from the group consisting of SEQ ID NO: 97, SEQ ID NO: 99, SEQ ID NO: 101, SEQ ID NO: 103, SEQ ID NO: 105, SEQ ID NO: 107, SEQ ID NO: 109, SEQ ID NO: 111, SEQ ID NO: 113, SEQ ID NO: 115, SEQ ID NO: 117, SEQ ID NO: 119, SEQ ID NO: 121, SEQ ID NO: 123, SEQ IDNO: 125, and SEQ IDNO: 127; does not reasonably provide enablement for any other embodiment as recited in the claims. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims. Applicants' arguments filed 01/22/2007 have been considered but are not persuasive for the reasons of record as supplemented below.

The nature and breadth of the amended claims encompass any isolated lectin polypeptides of any amino acid sequence and structure consisting of any truncated mammalian UDP-GalNAc:polypeptide N-acetylgalactosaminyltransferase comprising any domain selected from the group consisting of the lectin domain of any mammalian UDP-GalNAc:polypeptide N-acetylgalactosaminyltransferase, any lectin-functional variant and fragments thereof

While, the specification provides guidance and examples for HIS-tagged truncated GalNAc-T2 and -T4 lectins consisting of the SEQ ID NO: 99 and SEQ ID NO: 103, respectively, as shown in Example 3, the specification does not provide guidance, prediction, and working examples for making any other isolated lectin polypeptide as recited in the claims. The specification does not provide guidance, prediction, and working examples showing that truncating any UDP-GalNAc:polypeptide N-acetylgalactosaminyltransferase such that it does not have the catalytic domain will result in a polypeptide that still has lectin binding activity.

Thus, an undue amount of trial and error experimentation must be preformed to search and screen for any and all UDP-GalNAc:polypeptide N-acetylgalactosaminyltransferases; and determining whether truncating it will result in the production a polypeptide that retains the ability to bind lectins. General teaching regarding screening and searching for the claimed invention is not guidance for making the claimed invention.

In view of the above considerations, the specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with the claims.

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***Conclusion***

10. No claims are allowed.

11. Claims 6 and 41-43 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

12. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christian L Fronda whose telephone number is (571)272-0929. The examiner can normally be reached Monday-Friday between 9:00AM - 5:00PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapura N Achutamurthy can be reached on (571)272-0928. The fax phone number for the organization where this application or proceeding is assigned is (571)273-8300.

14. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000. CLF

  
**TEKCHAND SAIDHA**  
**PRIMARY EXAMINER**